

## REMARKS

Claims 53-60 are presently pending in the case. Claims 69-86 have been cancelled without prejudice or disclaimer. The claims were withdrawn from consideration by the Examiner as being drawn to a non-elected invention. Applicant reserves the right to pursue the claims in a divisional application. Claim 53 has been amended. The amendment is supported by the specification as originally filed. For example, see *inter alia* page 26 lines, 24-31; page 29, lines 29-34; and page 32, lines 19-33.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

### **Claim rejections under 35 USC 102**

The Examiner rejected claims 53-55, 57 and 59 under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,727,546 to Clarke et al. (hereinafter Clarke et al.). The rejection is traversed.

Clark et al. does not anticipate claims 53-55, 57 and 59. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Independent claim 53, for example, is to a method for aerosolizing a pharmaceutical formulation, the method comprising, *inter alia*, providing a valve to prevent respiratory gases from flowing to the lungs when a user attempts to inhale, and then abruptly permitting respiratory gases to flow to the lungs by opening the valve when a threshold actuating vacuum caused by the attempted inhalation is exceeded, and providing a flow regulator within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases. Clarke et al. does not provide both a threshold valve as claimed and a flow regulator as claimed. It is respectfully submitted that this positively recited feature is absent in the disclosure of Clarke et al., thereby

precluding a section 102 rejection because each and every element of the claim is not taught by the cited reference.

The Examiner directs the Applicant's attention to the embodiment of Clarke et al. shown in Figures 2(a)-2(c). However, this embodiment of Clarke et al. also fails to disclose all positively set forth features set forth in claim 53. For example, claim 53 recites that the flow resistance through the flow regulator is low when the respiratory gases are permitted to flow and increases when the vacuum generated by the user increases. The Clarke et al. device does not operate in this manner. In going from the position shown in Clarke et al.'s Figure 2(a) to the position shown in Figure 2(b), the flow resistance decreased, i.e. the opening caused by the movement of element 27 increases. Thus, the flow resistance is not low when gases are permitted to flow than then increases, as required by claim 53. Thus, Clarke et al. fails to anticipate claim 53 for this additional reason.

Applicant requests withdrawal of the rejection of claim 53 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of the rejection of claims 54, 55, 57 and 59 which depend from claim 53 and are not anticipated by Clarke et al. for at least the same reasons as claim 53.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 58 and 60 under 35 USC 103(a) as being unpatentable over Clarke et al. The rejection is traversed.

Clarke et al. does not render claims 58 and 60 unpatentable. Claims 58 and 60 depend from claim 53 which is not rendered unpatentable by Clarke et al. for the reasons given above. Since claims 58 and 60 depend from an allowable claim, they too are allowable. In addition, claim 58 is allowable over Clark et al. in that Clarke et al. fails to disclose or teach the duckbill valve recited in the claim. Claim 60 is also not

rendered unpatentable by Clarke et al. in that claim 60 recites a parallel flow arrangement that is not disclosed or taught by Clarke et al.

The Examiner rejected claim 56 under 35 USC 103(a) as being unpatentable over Clarke et al. in view of U.S. Patent No. 6,116,237 to Schultz et al. (hereinafter Schultz et al.). The rejection is traversed.

Claim 56 depends from allowable claim 53. Since Schultz et al. does not make up for the deficiencies discussed above with regard to Clarke et al., the combination of Clarke et al. and Schultz et al. also fails to render claim 56 unpatentable.

## Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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